K112844

OCT 27 2011

05 510(k) summary

21CFR807.92 / special 510(k)

Name of the legally marketed (unmodified) device

Proprietary name:	RehaStim;
	RehaMove (RehaStim with movement exerciser)
510(k):	K073237
Device Class:	class 2 device
Classification:	Neurology

Submitter's / owner's name, address, Telephone number, a contact person, and the date the summary was prepared:

510k Submitter:	Hasomed GmbH
Contact person:	Matthias Weber
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	39114 Magdeburg
	Germany
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Prepared on September 26 2011

Name of device, including the trade or proprietary name if applicable, the common or usual name, and the classification name :

Proprietary name: "RehaStim 2" of HASOMED GmbH

"RehaMove 2" (movement exerciser with arm crank, includes RehaStim) of HASOMED GmbH

Common Name: Powered Muscle Stimulator

Classification Name: Powered Muscle Stimulator

Identification of the legally marketed device to which the submitter claims equivalence:

Manufacturer: HASOMED GmbH

Product: "RehaStim" ; "RehaMove" (Version 1)

K-number: K073237

Class: class 2 device

Product Code: GZI

A description of the device that is the subject of the premarket notification submission:

The RehaMove 2 is a portable Functional Electrical Stimulation (FES) system based on a cycle ergometer and a stimulator. It consists of: a motorized movement exerciser (MOTO Med viva II) produced by Reck-company and a stimulator unit (RehaStim 2) produced by Hasomed GmbH. For alternative training of upper extremities a motorized arm crank with same characteristics can be used. The stand-alone mode of RehaStim 2 allows training without movement exerciser.

The system RehaMove 2 allows training for person with impaired functions of lower and upper extremities in two modes:

active mode - using FES support for muscle contractions and if necessary motor power of movement exerciser

passive mode - only movement by motorized movement exerciser

The FES – stimulation controller RehaStim 2 generates impulses, on up to 8 channels simultaneously, to activate paralyzed muscles via surface electrodes. A connection cable enables the RehaStim to receive angle-parameters and to control the Reck Viva II movement exerciser. Two electrode cables (at maximum 16 cutaneous electrodes for 8 channels) connect the RehaStim 2 with the electrodes on the skin. A USB interface gives the possibility to connect the RehaStim 2 to the PC e.g. connect to patient database.

The RehaStim 2 can be used as a portable (contains a battery) or stationary device for training and rehabilitation applications.

Statement of the intended use of the device:

Both the RehaStim 2 and RehaMove 2 are intended for general rehabilitation for:

1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Maintaining or increasing range of motion

Technological Characteristics

The functions of the RehaMove 2 and RehaStim 2 are the same as the predicate device however there are certain technological similarities and differences as described below:

Technology	RehaStim 2 / RehaMove 2	RehaStim/RehaMove
Power Source	AC and/or storage battery: Power supply: cincon tr30m according to EN60601-1 Battery: BMZ18650 V, Li-Ion Mangan cells, 2S1P, C= 1600 mAh,	AC and/or storage battery: Power supply :mascot typ9920 according to EN60601-1 Battery: SANYO, NiMh, C= 2700 mAh
Controller	Uses custom processor, running LinuxOS ,running custom software	Uses custom controller running custom software
Stimulator (energy delivered)	0-130mA charge balanced stimulator with rectangular impulses	0-130mA charge balanced stimulator with rectangular impulses
patient part	Type: BF	Type: BF
movement exerciser	RehaMove 2: Uses motor to create flywheel effect with reduced weight and space	RehaMove: Uses motor to create flywheel effect with reduced weight and space
Arm crank	Arm crank gives same upper extremities training possibilities as with lower extremities Uses motor to create flywheel effect with reduced weight and space	Arm crank gives same upper extremities training possibilities as with lower extremities Uses motor to create flywheel effect with reduced weight and space

Seating	Allows user to remain in their own seating, e.g. wheelchair eliminating the need for transfer	Allows user to remain in their own seating, e.g. wheelchair eliminating the need for transfer
Passive cycling	RehaMove 2: Utilizes motor to provide assistance during passive cycling	RehaMove: Utilizes motor to provide assistance during passive cycling
Database interface	Utilizes database interface for storage and retrieval of patient therapy settings and storage of session logs	Utilizes database interface for storage and retrieval of patient therapy settings and storage of session logs

Table 5-1 Technological similarities and differences

Determination of substantial equivalence

Test or procedure	Task
Review of user documentation for predicate device	It was reviewed that equivalent function-nality was implemented in RehaMove 2.
Review of 510(K) submissions for predicate device	Confirm technical specifications for completion of predicate details in comparison tables
Output characteristic measurement of new device	The RehaMove 2 / RehaStim 2 device was tested and technically compared with the predicate device.
Control of system testing	The system testing was aligned to verify performance to specification.

Table 5-2 Performance data

It can be matched that there is a substantial equivalence in all important technical and medical characteristics to the premarket notification.

HASOMED concludes that:

Both the RehaMove 2 and RehaStim 2 have the same intended use and the same output characteristics as the predicate device. The different technological characteristics do not raise new questions of safety and effectiveness.

The safety and effectiveness of using a movement exerciser to simulate the predicate devices motor powered flywheel and provide passive cycling assistance has been extensively demonstrated in particular by the ongoing clinical use of the movement exerciser without the stimulation component both in the European Union and the U.S.A.

The safety and effectiveness of the controller has been demonstrated over the development period of the RehaStim 2 and RehaMove 2 and many clinical applications.

The remote database enhances the safety and effectiveness of the system by ensuring that patients always starts a therapy session with their latest, accurate device settings.

In conclusion, HASOMED´s clinical and non- clinical testing have demonstrated that the RehaStim 2 and RehaMove 2 are as safe and effective as the predicate device.

Product code: GZI

Common Name: Powered Muscle Stimulator

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

OCT 2 7 2011

Hasomed GMBH
% Mr Matthias Weber
HASOMED GmbH
Paul-Ecke-Strasse 1
39114 Magdeburg
Germany

Re: K112844
Trade/Device Name: RehaMove 2 & RehaStim 2
Regulation Number: 21 CFR 882.5810
Regulation Name: External functional neuromuscular stimulator
Regulatory Class: Class II
Product Code: GZI
Dated: September 27, 2011
Received: September 29, 2011

Dear Mr. Weber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

04 Indications for Use

510k number if known: K112844

Device Name: RehaMove 2

RehaStim 2 (stand alone)

Indications for Use:

Both the RehaMove 2 and RehaStim 2 are intended for general rehabilitation for:

1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Maintaining or increasing range of motion

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K112844